



Device Classification

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What Is the Purpose of This Panel Meeting?

To provide input to FDA on the classification of preamendments device types and whether FDA should call for PMAs or reclassify to Class II or Class I.

To provide input to FDA on the reclassification of a postamendment device that has been approved through the PMA process as Class III.

What Is a Preamendments / Postamendments Device?

Preamendments: A device that was introduced into interstate commerce prior to May 28, 1976 (the enactment date of the Medical Device Amendments)

Postamendments: Devices that were not in commercial distribution prior to May 28, 1976

What Is the Classification Process?

Recent legislation (FDASIA) has affected the classification of medical devices (including Class III 510(k)s) and FDA must now:

- Publish a proposed order announcing our proposed classification and seek public comment
- Hold a panel meeting if classifying or reclassifying a device type
- Consider comments and all available information, including panel recommendations, prior to issuing a final order finalizing the classification of the device type

What Are the Device Classes?

- Classified based on controls necessary:
 - Class I - General Controls
 - Class II - General and Special Controls
 - Class III - Premarket Approval
- A device should be placed in the lowest class whose level of control provides reasonable assurance of safety and effectiveness

What Are General Controls?

- General Controls Include:
 - Prohibition against adulterated or misbranded devices,
 - Good Manufacturing Practices (GMPs),
 - Registration of manufacturing facilities,
 - Listing of device types,
 - Recordkeeping, etc.

What Are Special Controls?

Special Controls include:

- Performance standards
- Postmarket surveillance
- Patient registries
- Development and dissemination of guidelines, etc.

What Are Class I Devices?

- Devices for which general controls are sufficient to provide reasonable assurance of the safety and effectiveness
 - Class I devices typically require no FDA premarket review prior to being marketed
 - Class I devices are also typically exempt from many quality system requirements (design controls)

What Are Class I Devices? (cont)

- Devices which cannot be classified into Class III:
 - Because they are not life sustaining, life supporting, of substantial importance in preventing impairment of public health, and
 - Because they do not present a potential unreasonable risk of illness or injury
- And which cannot be classified into Class II:
 - Because insufficient information exists to establish special controls to provide a reasonable assurance of safety and effectiveness

What Are Some Examples of Class I Devices?

- General Cardiovascular Surgical Instruments
- Adhesive Bandages
- Manual Stethoscope
- Crutches

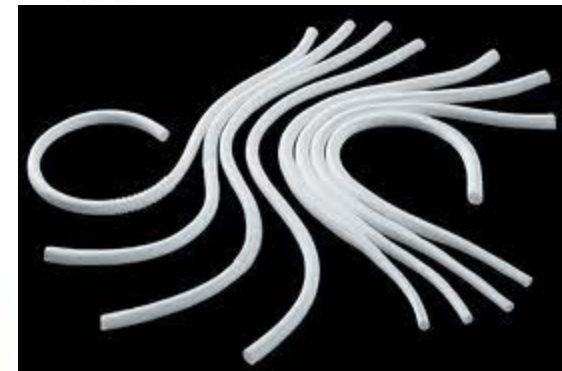


What Are Class II Devices?

- Cannot be classified into Class I:
 - because general controls are insufficient to provide reasonable assurance of the safety and effectiveness of such device, and
 - for which there is sufficient information to establish special controls to provide such assurance
- Class II devices typically require premarket notification (510(k)) to FDA prior to being marketed

What Are Some Examples of Class II Devices?

- Blood Pressure Cuffs
- Percutaneous Catheters
- Electronic Stethoscope
- Vascular Graft Prosthesis
- Echocardiograph (ECG)
- Hemodialysis System
- Syringes



How Are Special Controls Used?

- As an example, PTCA catheters were reclassified from Class III to Class II (special controls)
- FDA issued a special controls guidance to mitigate risks to health:
 - Biocompatibility testing
 - Bench testing
 - Animal testing
 - Sterility and shelf life
 - Labeling (warnings, precautions, adverse effects, etc.)
- These special controls, in combination with the general controls, provide reasonable assurance of safety and effectiveness
- Companies must provide evidence in their 510(k) submissions of how the special controls were addressed

What Are Class III Devices?

- Cannot be classified into Class II because:
 - insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness, and
 - The devices are:
 - life sustaining and/or life supporting, or
 - of substantial importance in preventing impairment of human health; or
 - presents potential unreasonable risk of illness or injury
- Class III devices typically require premarket approval (PMA) prior to being marketed

What Are Some Examples of Class III Devices?

- Endovascular Grafts
- Coronary and Peripheral Stents
- Percutaneous Heart Valves
- Left Ventricular Assist Devices (LVADs)
- Cardiac Occluders
- Implantable Pacemakers



What Are “Class III 510(k)” Devices?

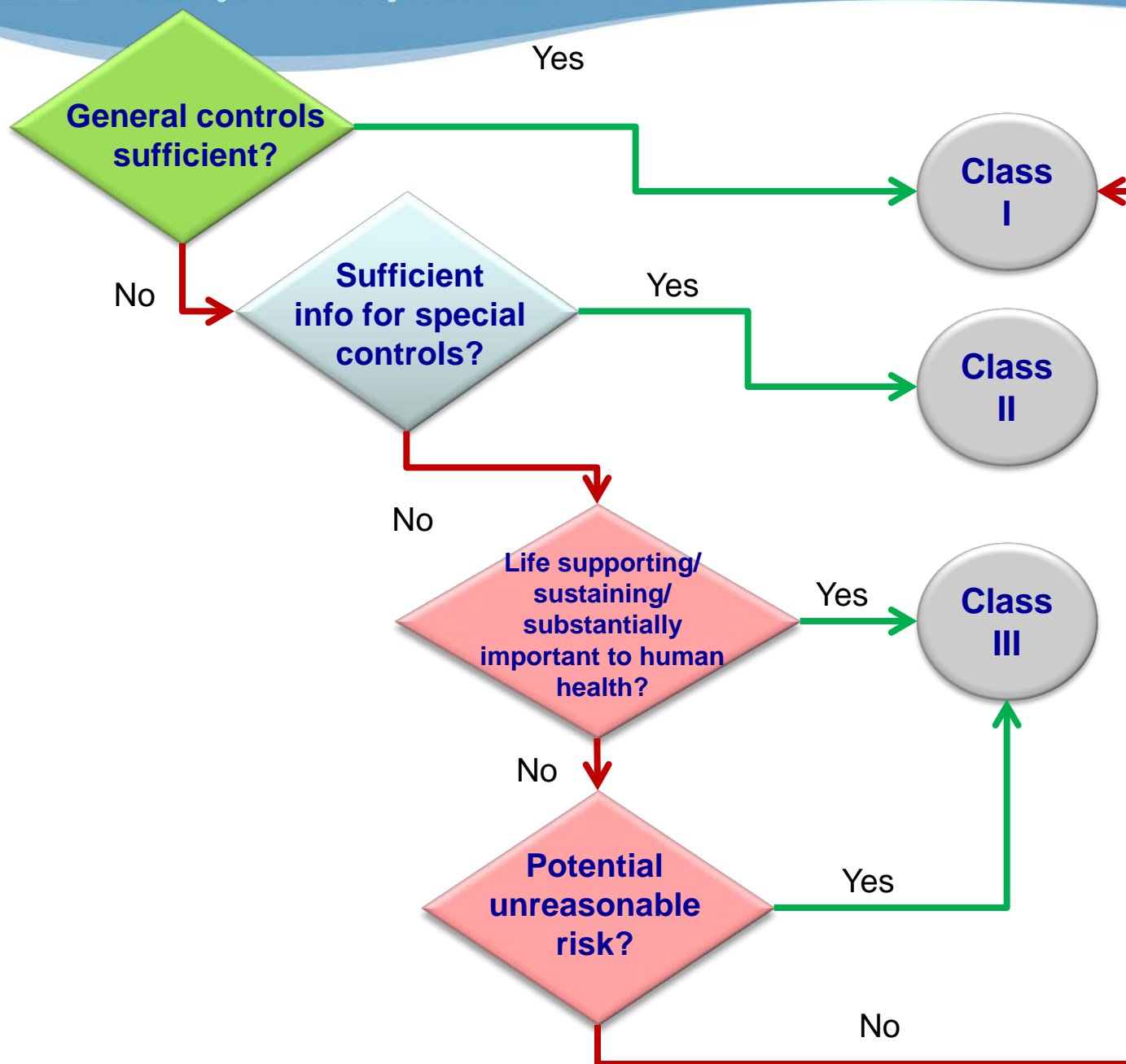
- Preamendments devices where FDA issued a proposed rule classifying them as Class III; however:
 - No final rule was issued, or,
 - A final rule was issued for Class III, but the rule did not contain a date by which companies were required to submit a PMA
- Therefore, these Class III devices are allowed to proceed to market via the 510(k) process until such time as either a call for PMAs or a reclassification is finalized

What Is the Reclassification Process?

- FDA may reclassify a *preamendment* device:
 - in a proceeding that parallels the initial classification proceeding
 - based upon new information respecting a device either on FDA's own initiative or upon the petition of an interested person
 - the Agency classifies or reclassifies intended uses which have actually been reviewed by the Agency

What is the Reclassification Process? (cont.)

- FDA may reclassify a *postamendment* device:
 - based upon new information respecting a device either on FDA's own initiative or upon the petition of an interested person
 - if sufficient regulatory controls exist to provide reasonable assurance of safety and effectiveness
 - may consult with an advisory committee
 - the Agency reclassifies intended uses which have actually been reviewed by the Agency



What Input do we Need from the Panel?

- Input on classification of the device(s) that are the subject of the Panel session
- Input should include:
 - Identification of the risks to health (if any) presented by the device
 - Whether the device is life-supporting/life-sustaining, of substantial importance in preventing impairment to human health, or presents a potential unreasonable risk of illness or injury
 - Whether sufficient information exists to develop special controls
 - Identification of special controls
 - Whether general controls alone are sufficient

What Will Happen After This Panel Meeting (Preamendments Devices)?

- FDA will consider the available evidence, including the input of this panel and the public comments
- FDA will issue a proposed order, proposing classification/reclassification of the device and seeking public comment
 - FDA may propose that the device type be reclassified or remain in Class III (call for PMAs), or split the classification based on indications or technology
- FDA will issue a final order identifying the appropriate class
 - If Class I or Class II, devices may continue to be marketed
 - If Class III, existing devices will remain on the market, but must submit a PMA by a specified time to continue marketing.
 - If PMA is not approved, devices will be considered misbranded and must be removed from distribution

What Will Happen After This Panel Meeting (Postamendments Devices)?

- FDA will consider the available evidence, including the input of this panel and the public comments
- If FDA believes the device can be reclassified, FDA will propose reclassification of the device and seek public comment
 - if FDA does not believe reclassification is warranted, no further action is taken and the device remains Class III requiring PMA
- Where appropriate, FDA will issue a final reclassification for the device
 - Existing devices may continue to be marketed, subject to general and any identified special controls. If Class II, not exempt, future devices of this type or changes to existing devices will be cleared for marketing via 510(k)'s.